

Ad hoc announcement pursuant to Art. 53 LR

Basel, 22 July 2021

Roche reports good half-year results

- **Group sales** up 8%¹ at constant exchange rates (CER); 5% in Swiss francs
- **Pharmaceuticals Division sales** decline 3%; sales grow 4% in the second quarter, following a first-quarter decrease of 9%; newly launched medicines (+30%) compensate for the continued impact from biosimilars
- **Diagnostics Division sales** grow 51% due to high demand for COVID-19 tests and strong momentum in routine testing
- **IFRS net income** increases by 2% (-3% in Swiss francs), while core earnings per share up 6%
- **Highlights** in the second quarter:
 - **Pipeline:** Positive study results for immunotherapy Tecentriq in early lung cancer; encouraging data strengthen Roche's portfolio in neurosciences and hard-to-treat blood cancers
 - **EU approvals:** Tecentriq (specific type of metastatic non-small cell lung cancer), Venclyxto-based combinations (acute myeloid leukaemia) and Enspryng (neuromyelitis optica spectrum disorder, a rare autoimmune disease of the CNS)
 - **GenMark Diagnostics:** Acquisition, completed in April, broadens Roche's molecular lab portfolio and reinforces our commitment to fight infectious diseases and antibiotic resistance
 - **COVID-19:** Additional positive study results for antibody combination Ronapreve (co-developed with Regeneron) and AT-527 (co-developed with Atea); Japan becomes first country to approve Ronapreve for the treatment of mild to moderate COVID-19; FDA Emergency Use Authorization for Actemra/RoActemra; launch of further tests reinforces Roche's position as a global leader in COVID-19 diagnostics
- **Outlook** for 2021 confirmed

Key figures	CHF millions		% change	
	2021	2020	At CER ¹	In CHF
January - June 2021				
Group sales	30,713	29,281	8	5
Pharmaceuticals Division	21,671	23,202	-3	-7
Diagnostics Division	9,042	6,079	51	49
Core operating profit	11,652	11,766	4	-1
Core EPS - diluted (CHF)	10.56	10.44	6	1
IFRS net income	8,216	8,465	2	-3

Commenting on the Group's performance in the first six months, Roche CEO Severin Schwan said: "We have achieved good results in the first half, primarily thanks to the demand for our new medicines and COVID-19 tests. The Pharma Division began to grow again in the second quarter. The base diagnostics business shows strong momentum. As expected, demand for COVID-19 tests peaked in the second quarter. I'm particularly excited about the significant progress we made in our product pipeline, including very promising study results for Tecentriq in early-stage lung cancer, as well as additional positive data for Evrysdi in spinal muscular atrophy and for COVID-19 medicines. Based on the good results of the first half of 2021, we confirm the outlook for the full year."

Outlook confirmed for 2021

Despite the continued strong impact of biosimilars, sales are expected to grow in the low- to mid-single digit range, at constant exchange rates. Core earnings per share are targeted to grow broadly in line with sales, at constant exchange rates. Roche expects to increase its dividend in Swiss francs further.

Group results

In the first half of the year, **Group** sales rose 8% (5% in CHF) to CHF 31 billion. IFRS net income increased 2% (-3% in CHF), while core earnings per share up by 6%. The appreciation of the Swiss franc against most currencies had a negative impact on the results expressed in Swiss francs compared to constant exchange rates.

Sales in the **Pharmaceuticals Division** were CHF 22 billion, a decrease of 3%. However, while sales in the first quarter were still strongly affected by COVID-19 (-9%), the second quarter showed signs of recovery in some regions (+4%). The ongoing impact from biosimilars, particularly in the US, resulted in a sales decrease of CHF 2.8 billion.

The new medicines (launched since 2012²) continued their strong growth (+30%, or +CHF 2.6 billion). In the first six months, they generated sales of over CHF 11 billion, thus already contributing more than 50% to the division's total sales.

In the **United States**, sales decreased by 8%, due to the launches of biosimilars for the cancer medicines MabThera/Rituxan, Avastin and Herceptin (combined -49% or CHF 1.7 billion) and the pandemic. This decline was partially compensated for by the new medicines – mainly Ocrevus (multiple sclerosis), Hemlibra (haemophilia), Evrysdi (spinal muscular atrophy) and Tecentriq (cancer immunotherapy). Here too, business is showing signs of recovery: after -14% in the first quarter, sales in the second quarter were stable, i.e. at the previous year's level.

Sales in **Europe** grew by 4%, with new product sales more than compensating for the impact from biosimilars and the pandemic. Ronapreve, the antibody combination against COVID-19, was the key growth driver, mainly in Germany, Italy and France.

In **Japan**, sales were stable. Growth of recently launched medicines, such as Tecentriq and Enspryng, was offset by the impact from biosimilars and government price cuts.

Sales in the **International region** grew by 2%. Growth in China (+3%) was mainly due to strong sales of Perjeta, Alecensa, Tecentriq and Herceptin, partly offset by biosimilar competition for Avastin and MabThera/Rituxan. Excluding China, sales increased by 1%, mainly due to orders for Ronapreve in India, again partially offset by the impact from biosimilars, mainly in Canada and Brazil.

The **Diagnostics Division** achieved very strong sales growth of 51% to CHF 9 billion. The base business (i.e. routine diagnostics), which was heavily impacted by the pandemic in 2020, grew strongly: +17% in the first quarter and +31% in the second quarter. Roche's industry-leading portfolio of COVID-19 tests contributed total sales of CHF 2.5 billion (CHF 0.7 billion in 2020); the demand for COVID-19 tests is likely to decrease in the second half of 2021.

The division recorded high sales growth in all regions: **Europe, Middle East and Africa** +70%, **Asia-Pacific** +44%, **North America** +25% and **Latin America** +77%.

In April, Roche acquired the US company **GenMark Diagnostics** for USD 1.9 billion. GenMark's novel technology detects a wide range of pathogens from a single patient sample. It broadens Roche's molecular lab portfolio, and reinforces our commitment to help control infectious diseases and antibiotic resistance.

Roche's response to the COVID-19 pandemic

Even with the availability of vaccines and declines in deaths from COVID-19 in various parts of the world, more treatment options are still needed. In the second quarter, Roche and/or its partners shared positive news:

- Antibody combination Ronapreve (co-developed with Regeneron): Preliminary phase III data from a University of Oxford-led trial demonstrated that the antibody combination casirivimab/imdevimab reduced the risk of death when given to patients hospitalised with severe COVID-19 who had not mounted a natural antibody response of their own. In July, Japan became the first country to approve Ronapreve for the treatment of patients with mild to moderate COVID-19.
- AT-527 (co-developed with Atea): Interim results from a phase II trial indicated rapid and sustained antiviral activity against SARS-CoV-2 in hospitalised COVID-19 patients. AT-527 continues to be evaluated for the treatment and prevention of COVID-19.

- Actemra/RoActemra:³ Roche's intravenous anti-inflammation medicine received FDA Emergency Use Authorization (EUA) for the treatment of severe COVID-19 in hospitalised adults and children.
- Manufacturing: Roche is currently ramping up its production capacity for AT-527, which requires a complex manufacturing process, as much as possible. For Actemra, Roche has already increased its own production capacity significantly and has been working with external manufacturers on transferring its technologies to increase the global supply further.

Roche has also reinforced its position as a world-leading supplier of COVID-19 diagnostics. In June, the **SARS-CoV-2 Antigen Self Test Nasal** obtained the CE mark,⁴ and the **cobas SARS-CoV-2 Nucleic acid test** for use on the cobas Liat System was granted first FDA EUA for PCR testing of both symptomatic and asymptomatic individuals at the point of care (with results within 20 minutes).

Pharmaceuticals: major approvals; positive data in neuroscience and oncology

In addition to all the efforts in the fight against the pandemic, Roche has continued to develop innovative medicines for other serious diseases. In the second quarter, Roche reported a number of regulatory achievements:

In May, the European Commission approved **Venclyxto**⁵-based combinations for adults with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy, and Tecentriq as a first-line monotherapy treatment for people with a specific type of metastatic non-small cell lung cancer.

In June, the FDA granted priority review for Roche's **Port Delivery System (PDS)** with **ranibizumab** for the treatment of neovascular or "wet" age-related macular degeneration. If approved, it would be the first and only eye implant with continuous drug delivery – an alternative to frequent eye injections.

Also in June, the European Commission approved **Enspryng** as the first and only at-home subcutaneous treatment for neuromyelitis optica spectrum disorder (NMOSD) for both adults and adolescents. NMOSD is a rare autoimmune disease of the central nervous system that can cause permanent blindness, muscle weakness and paralysis.

Furthermore, Roche presented positive data in neurosciences and oncology:

Roche's data across its growing neuroscience portfolio, presented at several medical congresses, demonstrates our continued commitment to developing breakthrough medicines for challenging neurological conditions. New data for **Enspryng** (NMOSD) and **Evrysdi** (spinal muscular atrophy, SMA) reinforced the efficacy and safety profile of both medicines, including early, very encouraging trial results for Evrysdi in pre-

symptomatic infants under two months of age. Data for **Ocrevus** (relapsing and primary progressive multiple sclerosis, MS) showed consistent benefit on slowing disease progression in both forms of MS.

In addition, Roche presented new data from 19 approved and investigational medicines across 20 cancer types at the American Society of Clinical Oncology congress. One of the highlights was the highly promising immunotherapy data in early lung cancer. It showed that **Tecentriq** improved disease-free survival in people with resectable early-stage non-small cell lung cancer compared to best supportive care – a first in cancer immunotherapy.

The latest advances with immunotherapies in non-Hodgkin lymphoma were also encouraging: data from the emerging T-cell engaging bispecific antibodies, **mosunetuzumab** and **glofitamab**, and the antibody-drug conjugate, Polivy, show the potential of these novel immunotherapeutic approaches for people with various types of blood cancer.

The outlook of Roche's haematology franchise was strengthened further with new data from three pivotal phase III studies. These data, presented at the annual haematology congress EHA, reinforced the efficacy of **Venclexta/Venclyxto** combinations in hard-to-treat blood cancers.

Pharmaceuticals: major clinical and regulatory news flow up to mid-July 2021

	Compound	Indication	Milestone
Regulatory	Xofluza	Influenza: Healthy people; high-risk people; post exposure	EU approval
	Evrysdi	Spinal muscular atrophy (SMA) type 1/2/3	EU approval
	faricimab	Diabetic macular oedema/neovascular age-related macular degeneration (nAMD)	US/EU joint filing
	Tecentriq	First-line PDL1+ non-small cell lung cancer (NSCLC)	EU approval
	Venclexta + azacitidine	Acute myeloid leukaemia	EU approval
Phase III / pivotal readouts	faricimab	nAMD	Ph III TENAYA/LUCERNE
	casirivimab/imdevimab	SARS-CoV-2 outpatient	Ph III study 2067
	casirivimab/imdevimab	SARS-CoV-2 post-exposure prophylaxis	Ph III study 2069
	Tecentriq	Adjuvant NSCLC	Ph III IMpower010
	Evrysdi	SMA type 1/2/3 switching study	Ph II JEWELFISH

Diagnostics: important launches in cardiovascular and oncology

Providing accurate and timely testing has never been more vital. Roche continues to invest heavily in diagnostic innovation to help meet the changing demands of healthcare systems beyond COVID-19.

In April, Roche launched new ways (claim extensions) to use their **cardiovascular tests**, empowering clinicians to improve screening, diagnosis and treatment of millions of people. These gold standard biomarkers have proven to be successful in supporting cardiovascular disease management and can help clinicians diagnose heart attacks (Troponin T) and manage heart failure more effectively (NT-proBNP).

Also in April, Roche received US approval for the first companion diagnostic, **VENTANA MMR RxDx Panel**, to identify cancer patients best suited for treatment with a specific GSK immunotherapy.

Pharmaceuticals sales

Sales	CHF millions		As % of sales		% change	
	2021	2020	2021	2020	At CER	In CHF
January - June 2021						
Pharmaceuticals Division	21,671	23,202	100.0	100.0	-3	-7
United States	10,802	12,464	49.8	53.7	-8	-13
Europe	4,485	4,190	20.7	18.1	4	7
Japan	1,808	1,908	8.3	8.2	0	-5
International*	4,576	4,640	21.2	20.0	2	-1

*Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Ocrevus	2,438	23	1'849	18	422	38	-	-	167	60
Perjeta	1,968	5	703	-3	578	-1	132	-6	555	28
Avastin	1,645	-40	530	-47	257	-69	330	-4	528	-12
Actemra/RoActemra	1,642	17	689	6	456	16	182	6	315	63
Tecentriq	1,599	29	811	16	339	17	257	84	192	68
Herceptin	1,396	-35	348	-56	277	-25	43	-40	728	-19
Hemlibra	1,393	45	837	34	292	95	166	16	98	138
MabThera/Rituxan	1,379	-41	855	-46	134	-35	20	-35	370	-27
Kadcyla	959	19	401	6	336	27	60	56	162	31
Xolair	887	-1	887	-1	-	-	-	-	-	-

* Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

Pharmaceuticals: established products

Avastin (CHF 1.6 billion -40%). Advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, relapsed glioblastoma (a type of brain tumour) and liver cancer in combination with Tecentriq. Sales were strongly impacted by the launch of biosimilars, mainly in the US and Europe.

Actemra/RoActemra (CHF 1.6 billion, +17%). Rheumatoid arthritis, forms of juvenile idiopathic arthritis and giant cell arteritis as well as CAR T cell-induced severe or life-threatening cytokine release syndrome. Growth was driven by the fact that a number of countries included this medicine in their treatment guidelines for severe COVID-19-associated pneumonia. The International region and Europe were the major contributors to this sales increase.

Herceptin (CHF 1.4 billion, -35%). HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales decrease was mainly due to biosimilar launches in the US and Europe.

MabThera/Rituxan (CHF 1.4 billion, -41%). Forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales were lower due to the biosimilar erosion as well as COVID-19 pandemic restrictions.

Xolair (CHF 887 million, -1%, US only). Chronic idiopathic urticaria and allergic asthma. Sales growth in the chronic idiopathic urticaria indication was offset by competition in the allergic asthma indication. Xolair remains the market leader in the larger allergic asthma indication.

Lucentis (CHF 665 million, -3%, US only). Eye conditions, including ‘wet’ age-related macular degeneration. Sales decreased, based on the continued impact of the COVID-19 pandemic (patients delaying treatment).

Pharmaceuticals: medicines launched since 2012

Ocrevus (first approved in 2017; CHF 2.4 billion, +23%). Relapsing and primary progressive forms of multiple sclerosis; 2-hour only infusion. The demand for this treatment in both indications remained strong, while the pandemic still had a certain negative impact. In the US, growth was driven both by new and returning patients, with a higher proportion of sales coming from returning patients.

Perjeta (first approved in 2012; CHF 2 billion, +5%). HER2-positive breast cancer. Sales increased mostly due to the high demand in China in both early and metastatic breast cancer settings.

Tecentriq (first approved in 2016; CHF 1.6 billion, +29%). Cancer immunotherapy for various types of cancer (either alone or in combinations), e.g. certain types of lung, bladder, breast and liver cancer. Sales growth in all regions, notably Japan, primarily due to the growth in the treatment of hepatocellular carcinoma (HCC). In the US, sales were higher driven by the new indications for first-line non-small cell lung cancer (NSCLC) and HCC.

Hemlibra (first approved in 2017; CHF 1.4 billion, +45%). Haemophilia A with and without factor VIII inhibitors; only prophylactic treatment that can be administered subcutaneously once weekly, every two or every four weeks. Sales continued to show a strong uptake, especially in the US and Europe.

Kadcyla (first approved in 2013; CHF 959 million, +19%). HER2-positive breast cancer. Sales growth was driven by Kadcyla’s usage in the early breast cancer setting. Sales benefited from patients switching to the new standard of treatment.

Alecensa (first approved in 2015; CHF 631 million, +20%). ALK-positive non-small cell lung cancer. The global uptake continued with sales growth across all regions; the International Region and Europe were the main drivers.

Ronapreve (first approved in 2021; FDA EUA in 2020 for Regeneron; CHF 595 million*). Antibody combination casirivimab/imdevimab for the treatment of recently diagnosed high-risk patients with mild to moderate COVID-19. Roche and Regeneron are collaborating on developing and manufacturing the medicine; Roche is responsible for distribution in Europe and other countries outside the US. There was a strong uptake, mainly in Germany, India, Italy and France.

Esbriet (first approved in 2014; CHF 526 million, -3%). Idiopathic pulmonary fibrosis (IPF).

Gazyva/Gazyvaro (first approved in 2013; CHF 324 million, +8%). Chronic lymphocytic leukaemia, rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma.

Evrysdi (first approved in 2020; CHF 243 million*). Spinal muscular atrophy (SMA) in adults and children two months of age and older. Evrysdi helps infants to survive without permanent ventilation; the first and only medicine for SMA that can be taken at home. The new SMA medicine continued to show a strong uptake, mainly in the US and Russia.

Erivedge (first approved in 2012; CHF 127 million, -9%). Advanced basal cell carcinoma.

Phesgo (first approved in 2020; CHF 96 million*). Early and metastatic HER2-positive breast cancer (fixed-dose combination of Perjeta and Herceptin for subcutaneous injection). Offers faster administration in just minutes, compared to hours with standard intravenous administration.

Polivy (first approved in 2019; CHF 94 million, +17%). Relapsed or refractory diffuse large B-cell lymphoma; part of combination therapy; a fixed-duration treatment option for people with this aggressive form of lymphoma.

Enspryng (first approved in 2020; CHF 39 million*). Rare autoimmune disease of the central nervous system (neuromyelitis optica spectrum disorder; NMOSD); first subcutaneous NMOSD treatment that can be self-administered at home. The medicine continues to show a good uptake, despite COVID-19 restrictions having some impact on potential new patients.

Rozlytrek (first approved in 2019; CHF 22 million, +182%). Specific form of non-small cell lung cancer (NSCLC); solid tumours expressing a specific gene fusion; ROS1-positive, advanced NSCLC.

* recently launched, no growth figures available

Diagnostics sales

Sales January - June 2021	CHF millions		As % of sales		% change	
	2021	2020	2021	2020	At CER	In CHF
Diagnostics Division	9,042	6,079	100.0	100.0	51	49
Customer Areas						
Core Lab	3,726	2,821	41.2	46.4	34	32
Molecular Lab	2,216	1,558	24.5	25.6	45	42
Point of Care	1,616	360	17.9	5.9	349	349
Diabetes Care	894	832	9.9	13.7	10	7
Pathology Lab	590	508	6.5	8.4	20	16
Regions						
Europe, Middle East, Africa	4,144	2,408	45.8	39.5	70	72
North America	2,055	1,740	22.7	28.8	25	18
Asia-Pacific	2,293	1,588	25.4	26.1	44	44
Latin America	550	343	6.1	5.6	77	60

Core Lab. Focuses on central labs; provides diagnostics solutions in the areas of immunoassays, clinical chemistry and custom biotech. Sales increased by 34%, due to the ongoing recovery of routine testing in all regions (with the largest contribution coming from Asia-Pacific) and COVID-19-related testing. Its immunodiagnostics business grew 40%.

Molecular Lab. Focuses on molecular labs; provides diagnostics solutions for the detection and monitoring of pathogens, donor screening, sexual health and genomics. Sales grew by 45% led by COVID-19 testing, such as the high-throughput PCR tests. Its virology business grew 60%. Sales were higher in all regions, led by the EMEA region and North America.

Point of Care. Focuses on diagnostics solutions at the point of care, e.g. in emergency rooms, medical practices or directly with patients; includes SARS-CoV-2 rapid tests, blood gas and electrolyte tests. Significant sales growth of 349%; the SARS-CoV-2 Rapid Antigen test was the main growth driver, especially in the EMEA region.

Diabetes Care. Focuses on integrated personalised diabetes management for people with diabetes and healthcare professionals. Sales increased by 10%, driven by its blood glucose monitoring business (such as the Accu-Chek Guide system).

Pathology Lab. Focuses on pathology labs; provides diagnostics solutions for tissue biopsies and companion diagnostics. Sales increased by 20%. This was mainly due to growth in the advanced staining and in the companion diagnostics businesses.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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This document contains certain forward-looking statements. These forward-looking statements may be identified by words such as 'believes', 'expects', 'anticipates', 'projects', 'intends', 'should', 'seeks', 'estimates', 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this Annual Report, such as: (1) pricing and product initiatives of competitors; (2) legislative and regulatory developments and economic conditions; (3) delay or inability in obtaining regulatory approvals or bringing products to market; (4) fluctuations in currency exchange rates and general financial market conditions; (5) uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side effects of pipeline or marketed products; (6) increased government pricing pressures; (7) interruptions in production; (8) loss of or inability to obtain adequate protection for intellectual property rights; (9) litigation; (10) loss of key executives or other employees; and (11) adverse publicity and news coverage. The statement regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche's earnings or earnings per share for 2020 or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche

References

[1] Unless otherwise stated, all growth rates and comparisons to prior year in this document are at constant exchange rates (CER: average 2020) and all total figures quoted are reported in CHF.

[2] Launched since 2012: Erivedge, Perjeta, Kadcyła, Gazyva/Gazyvaro, Esbriet, Cotellix, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, Rozlytrek, Phesgo, Enspryng, Evrysdi and Ronapreve (casirivimab/imdevimab).

[3] Actemra/RoActemra is currently not approved for this use.

[4] An early version has already been available in a number of European countries since February 2021 (local special approval pathways).

[5] Venclexta/Venclexto is being developed by AbbVie and Roche.

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